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FRENCH REPUBLIC  
NATIONAL INSTITUTE  
OF INDUSTRIAL PROPERTY

(11) Publication No.:

2 447 406

PARIS

A1

**PATENT APPLICATION**

(21)

**No. 80 05003**

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(54) **Surgical Cryogenic Probe**

(51) **International Classification (Int. Cl. <sup>3</sup>): A 61 B 17/36**

(22) **Filing date:..... March 6, 1980**

(33) (32) (31) **Priority claims:**

(41) **Application publication date..... B.O.P.I. "Listes", No. 37, 09.11.1981**

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(71) **Applicant: COMMISSARIAT A L'ENERGIE ATOMIQUE, France**

(72) **Inventors: Bernard Gravil, Albert Lacaze, Patrick Le Pivert, and Gilbert Sauvigne**

(73) **Owner: See (71)**

(74) **Attorney: Brevatome,  
25, rue de Ponthieu, 675008, Paris**

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The present invention relates to a surgical cryogenic probe that allows diseased cells to be destroyed by freezing them.

More specifically, the invention deals with a compact cryogenic probe that is designed for use with an endoscope in such a manner as to assure freezing of diseased internal cells such as cancerous cells of human organs.

Conventional prior art cryogenic probes are used, mainly because of their large size, for destruction of diseased cells of the skin or directly accessible organs.

These prior art cryogenic probes comprise a rigid probe body that is generally composed of two concentric tubes, with an insulating annular space defined between the two tubes, a supply line in the form of two concentric tubes: a capillary inner tube and an outer tube, in which a refrigerant fluid can circulate to be discharged at one end of the body of the cryogenic probe, and a refrigerating head located at the end of the body of the cryogenic probe at which said refrigerant fluid is discharged, thus making it possible to refrigerate the cryogenic probe and to supply the necessary cooling power for freezing the cells. The cryogenic probes of this type cannot be adapted for use in conventional endoscopic procedures because of their large size and a rigid supply line.

The present invention relates to a surgical cryogenic probe that can eliminate the above disadvantages and that is designed for an endoscope to be used inside a human body.

This surgical cryogenic probe that comprises a body, a refrigerating head, and a supply line as described above is characterized by that:

- a body 2 of the cryogenic probe is provided with a heat exchanger that assures the indirect contact between a fluid that can circulate under high pressure in the inner capillary tube and a fluid that can circulate at a low pressure in the outer tube and in the body of the cryogenic probe;

- the supply line being a flexible supply line that has the inner capillary tube and the outer tube in which a fluid can circulate a temperature close to the ambient temperature and which are capable of withstanding high pressure.

According to another feature of the invention, the heat exchanger located in the body of the cryogenic probe comprises a counter-current heat exchanger that has a part thereof in contact with the refrigerating head.

The invention is further characterized by the fact that said supply line has a counter-current heat exchanger that surrounds, wholly or in part, the capillary tube of the supply line which is located in an appropriate annular space.

In a preferred embodiment of the invention, the cryogenic probe comprises a fluid flow control means.

In another embodiment of the invention, the cryogenic probe comprises an automatic fluid flow control means.

Further, according to the invention, the inner capillary tube is made of a metal alloy such as copper and nickel alloy, and the outer tube is made of plastic selected from the group of polyamides and polytetrafluoroethylenes.

Provision of the heat exchangers and a flexible supply line in which a fluid circulates at a temperature close to the ambient temperature allows the cryogenic probe to be used for internal organs of a human body to destroy diseased cells without disturbing the patient.

Other characteristics and advantages of the invention will become apparent from the description of illustrative non-limiting embodiments that follows, with reference to the accompanying drawings, in which:

Figure 1 schematically shows a first embodiment of a cryogenic probe according to the invention;

Figure 2 schematically shows a second embodiment of a cryogenic probe according to the invention;

Figure 3 schematically shows a third embodiment of a cryogenic probe according to the invention;

Figure 4 schematically shows a fourth embodiment of a cryogenic probe according to the invention;

Figure 5 schematically shows a sectional view taken along line A-A in Figure 1.

Figures 1, 2, 3, 4 show a cryogenic probe that has a rigid body 2 having an annular space 4 defined between a pair of concentric tubes 6 and 8 that are made, in this particular case, of stainless steel, a flexible supply line 10 that comprises a pair of concentric tubes: an inner capillary tube 12 in which a refrigerant fluid circulates under high pressure in the direction shown by arrow Fa

to be admitted at one end of the body 2 of the cryogenic probe and to be discharged at the other end through an expansion port 14 that is sized to have a low fluid flow when the cryogenic probe is cold, and an outer tube 16 in which a low-pressure fluid circulates in the opposite direction shown by arrow Fb. The outer tube 16 can be fixed to the body 2 of the cryogenic probe, e. g., by means of a barbed portion 18.

The inner capillary tube 12, which is preferably made of a metal alloy such as a copper and nickel alloy and can be used at high pressures (about 45 bar), and the outer tube 16, which is preferably made of plastic such as, for example, polyamide or polytetrafluoroethylene, define an annular space 20 between them. Figure 5 shows a cross-section of the supply line 10.

The cryogenic probe also has a refrigerating head 22 generally made of copper, which is provided at the end of the body 2 of the cryogenic probe where the refrigerant fluid is discharged. The refrigerating head 22 makes it possible to supply cold that is necessary to destroy the diseased cells by freezing when the refrigerant fluid expands. The cryogenic probe that is adaptable to an endoscope, according to the invention, is provided with a counter-current heat exchanger 24 accommodated within the body 2 of the cryogenic probe.

According to the first embodiment shown in Figure 1, a heat exchanger 24a comprises a stack of alternating layers 26 and 28 that are made of sintered and non-sintered powder or of two different materials, respectively, one of which is a heat conductor and the other is a heat insulator. The layers shown at 26 are preferably made of stainless steel, and the layers shown at 28 are preferably made of copper. The first sintered layer of copper 28', which encloses the expansion port 14 and is in contact with the refrigerating head 22, forms a large heat exchange surface between refrigerant fluid and the wall of the refrigerating head 22 of the cryogenic probe. The other alternating layers form the counter-current heat exchanger proper 24a for heat exchange between a warm high-pressure fluid, i. e., a fluid at a temperature close to the ambient temperature, which is admitted to the body of the probe 2, and a cold low-pressure fluid in such a manner that the temperature of the flexible supply line 10a cannot be too low. The refrigerant fluid used is nitrous oxide ( $\text{N}_2\text{O}$ ) that has a storage pressure

of 45 bar at the ambient temperature, which, when its pressure is reduced from 45 bar to 1 bar, causes a temperature reduction of more than 100K.

A cryogenic probe shown in Figure 2 is simpler than that shown in Figure 1 and has a counter-current heat exchanger 24b that is made up of two parts and that comprises a stack of fin discs 25 extending in parallel to each other, which are heat conductors. The capillary tube 12 of the supply line 10b is coiled and is brazed, e. g., with tin to a part of the heat exchanger 24b that is made up, e. g., as a stack of copper fin discs. This assembly (the part of the heat exchanger and the capillary tube) is cemented within the body 2 of the cryogenic probe to prevent the low-pressure fluid from by-passing the heat exchanger. The heat exchange surface between the fluid and the inside wall of the body 2 of the cryogenic probe is increased by provision of the fin discs 25 that form the other part of the heat exchanger 24b, which are welded to the body of the probe at the level of the refrigerating head 22 and which are in contact therewith. The fluid flow control can be effected by pinching the capillary tube 12 of the supply line 10b.

Figure 3 shows a third embodiment of a cryogenic probe. In this embodiment, similarly to that shown in Figure 1, the capillary tube 12 of the supply line 10c is positioned within a counter-current heat exchanger 24c housed in the body 2 of the cryogenic probe. The heat exchanger 24c is made as a single piece and comprises a stack of the heat conducting fin discs 25, the heat conducting discs 25 being welded to the body 2 of the cryogenic probe, in contact with the refrigerating head 22. In this embodiment, the cryogenic probe has a fluid flow control in the form of a tiny rod 30 inserted into the inner capillary tube 12 of the supply line 10c at the level of the refrigerating head 22 of the cryogenic probe, the rod being made, e. g., of copper. There is an expansion annular space 32 left around the rod 30 for passage of the warm refrigerant fluid under warm pressure.

The supply line 10c shown in Figure 3 has a counter-current heat exchanger 34 that surrounds, wholly or in part, the capillary tube 12 of the supply line 10c, the heat exchanger being positioned within the annular space 20 defined between the inner capillary tube 12 and the outer tube 16 of the supply

tube 10c. It is understood that a heat exchanger 34 that is made, e. g., similar to the heat exchanger 24c that is positioned in the body 2 of the cryogenic probe can be installed in the cryogenic probes shown in Figures 1, 2 and 4. The heat exchanger 34 makes it possible to maintain a temperature of the supply line 10c that is close to the ambient temperature in the easiest possible way.

Figure 4 shows a fourth embodiment of a cryogenic probe. This cryogenic probe comprises an automatic fluid flow control device 35. Automatic control is achieved by means of two interengaging parts. A first part 36 and a second part 38 are made of different materials that have a big difference between the coefficients of contraction. The two parts engage each other to define an overflow wall 40 for circulation and expansion of the warm fluid, the capillary tube 12 being discontinued between the first part 36 and the second part 38. The first part 36 is preferably made of invar metal, and the second part 38 can be made of plastic, brass, or aluminum. The space at the overflow 40 wall is large when the device is warm, i. e., at the ambient temperature, thus determining a low fluid head loss. As the temperature decreases, plastic, brass or aluminum contract to a greater extent compared to invar metal, whereby the space of the overflow wall 40 between the parts 36 and 38 decreases, thus resulting in an increase in the fluid head loss. It is understood that the fluid flow in the warm state will be greater to assure faster cooling. To prevent the warm fluid from bypassing the heat exchanger 24d in the zone of interruption of the capillary tube 12 of a supply line 10d, the cryogenic probe has a third part 42 that makes the part of the capillary tube 12 that terminates in the refrigerating head 44 integral with a wall 42 that is integral with the first part 36. The flow of fluid is shown in the drawing. In this embodiment, a heat exchanger 24d is made similar to that shown in Fig. 3. The annular space 20 is provided with the heat exchanger 34.

It should be also noted that control or automatic control of the fluid flow can be provided in the first embodiment of the cryogenic probe (Figure 1) and that the fluid flow control in the first three embodiments can be assured either by pinching the capillary tube 12 or by means of the rod 30.

In the embodiments shown in Figures 1, 2, and 3, the counter-current heat exchangers 24 and 34, which had not been used heretofore, allow a good heat exchange to be assured between the warm fluid that is admitted at high pressure through the capillary tube 12 and the cold fluid discharged at low pressure through the outer tube 16. In the embodiment shown in Figure 4, the heat exchanger 24d allows a good heat exchange to be had between the refrigerant fluid and the refrigerating head 22 of the cryogenic probe. The above arrangements improve the refrigerating performance upon expansion of the refrigerant fluid, which could not be achieved in the prior art devices.

Moreover, provision of the above-described heat exchangers and control or automatic control of the fluid flow allow faster cooling of the cryogenic probe to be achieved, with the cooling time that is as short as less than 15 seconds to obtain a temperature of  $-40^{\circ}\text{C}$  at a distance of 0.5 mm from the refrigerating head (the temperature that is necessary to achieve the guaranteed destruction of the cells by freezing them). This fast cooling is also possible, because the part of the heat exchanger 24 that is installed within the body of the cryogenic probe is in contact with the refrigerating head 22 of the probe.

In a specific form of realization of the cryogenic probe shown in Figure 4, the automatic fluid flow control 35 allows the constant flow of 600 L/hr to be obtained at normal temperature and pressure, whereby the time of operation with a bottle containing nitrous oxide can be doubled and even tripled.

The above-described cryogenic probe that is suitable for the endoscopic procedures has a very small size. As a matter of fact, the flexible supply line, which can be as long as two meters [about 7'] has a maximum diameter of four millimeters (with the diameter of the inner capillary tube of about 0.8 mm), with the rigid part of the cryogenic probe (the head and body) being approximately twenty millimeters long and having a maximum diameter of six millimeters. Moreover, the use of the flexible supply line that is capable of operating at high pressure of about 45 bar, which is provided with a counter-current heat exchanger 34, allows the fluid to be conveyed at the ambient temperature without disturbing the patient.

CLAIMS

1. A surgical cryogenic probe that is capable of destroying diseased cells by freezing, of the type comprising:

- a rigid body (2) having an annular insulating space (4) defined between two concentric tubes (6 and 8);

- a supply line (10) having two concentric tubes: an inner capillary tube (12) and an outer tube (16), the supply line having an annular space (20) that is defined between said two tubes for circulation of a refrigerant fluid in the annular space, the fluid being discharged at one end of the body (2) of the cryogenic probe where the fluid expands;

- a refrigerating head (22) located at said end of the body of the cryogenic probe to transmit the necessary freezing action to the cells, characterized by the fact that:

- the body (2) of the cryogenic probe is provided with a heat exchanger (24) with indirect contact between a fluid that can circulate at high pressure in the inner capillary tube (12) and a fluid that can circulate at low pressure in the outer tube (16) and in the body (2) of the cryogenic probe;

- the supply line (10) is a flexible supply line, in which the inner capillary tube (12) and the outer tube (16), in which the fluid can circulate at a temperature close to the ambient temperature, are capable of withstanding high pressure.

2. The cryogenic probe of claim 1, characterized by the fact that the heat exchanger (24) located in the body (2) of the cryogenic probe is a counter-current heat exchanger having a part thereof in contact with the refrigerating head (22).

3. The cryogenic probe of any of claims 1 and 2, characterized by the fact that the refrigerant fluid is nitrous oxide ( $N_2O$ ).

4. The cryogenic probe of any of claims 1 through 3, characterized by the fact that the supply line is provided with a counter-current heat exchanger (34) that surrounds, wholly or in part, the capillary tube (12) of the supply line (10) in the respective annular space (20).

5. The cryogenic probe of any of claims 1 through 4, characterized by the fact that the heat exchangers (24 and 34) are made as stacks of heat conducting fin discs (25).

6. The cryogenic probe of any of claims 1 through 4, characterized by the fact that the heat exchanger (24) of the body (2) of the cryogenic probe is made as a stack of layers (26 and 28) that consist of two alternating different materials: a heat conductor and a heat insulator, respectively.

7. The cryogenic probe of any of claims 1 through 6, characterized by the fact that it comprises a fluid flow control means.

8. The cryogenic probe of any of claims 1 through 6, characterized by the fact that it comprises an automatic fluid flow control means.

9. The cryogenic probe of any of claims 1 through 8, characterized by the fact that the inner capillary tube (12) is made of a metal alloy.

10. The cryogenic probe of claim 9, characterized by the fact that the inner capillary tube (12) is made of a copper and nickel alloy.

11. The cryogenic probe of any of claims 1 through 10, characterized by the fact that the outer tube (16) is made of plastic selected from the group of polyamides and polytetrafluoroethylenes.

12. The cryogenic probe of any of claims 1 through 11, characterized by the fact that the capillary tube (12) of the supply line (10) extends in the heat exchanger (24) that is installed in the body (2) of the cryogenic probe.

13. The cryogenic probe of any of claims 1 through 5 and claims 7 through 11, characterized by the fact that the capillary tube (12) of the supply line (10b) is coiled in a part of the heat exchanger (24) installed in the body (2) of the cryogenic probe.

14. The cryogenic probe of claim 6, characterized by the fact that the materials of the layers (26 and 28) are copper and stainless steel, the first layer that is in contact with the head (22) of the cryogenic probe being made of copper.

15. The cryogenic probe of claim 7, characterized by the fact that the fluid flow is controlled by means of a rod (30) inserted into the inner capillary tube (12) of the supply line (10) at the level of the refrigerating head (22) of the cryogenic probe.

16. The cryogenic probe of claim 7, characterized by the fact that the fluid flow is controlled by pinching the inner capillary tube (12) of the supply line.

17. The cryogenic probe of claim 8, characterized by the fact that automatic control of the fluid flow is achieved by means of two interengaging parts, with a first part (36) and a second part (38) being made of different materials that have a big difference in the coefficients of contraction, the two parts (36 and 38) being assembled with an overflow wall (40) defined between them for fluid circulation.

18. The cryogenic probe of any 17, characterized by the fact that the first part (36) is made of invar metal.

19. The cryogenic probe of claim 17, characterized by the fact that the second part (38) is made of plastic.

20. The cryogenic probe of any of claims 17 and 18, characterized by the fact that the second part (38) is made of aluminum.

21. The cryogenic probe of any of claims 17 and 18, characterized by the fact that the second part (38) is made of brass.

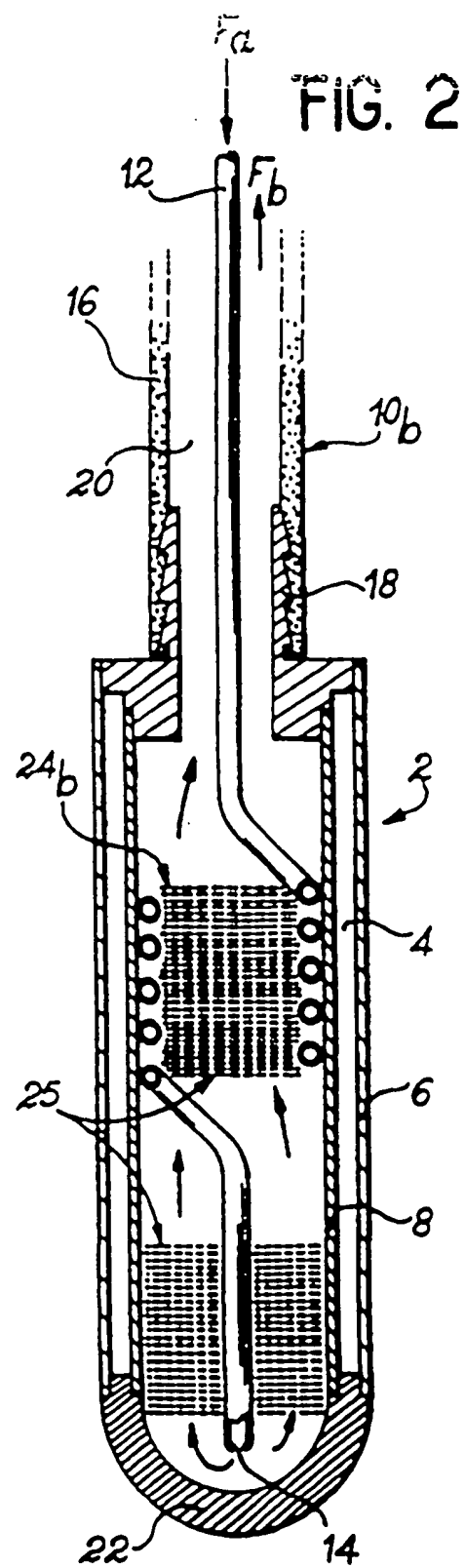


FIG. 3

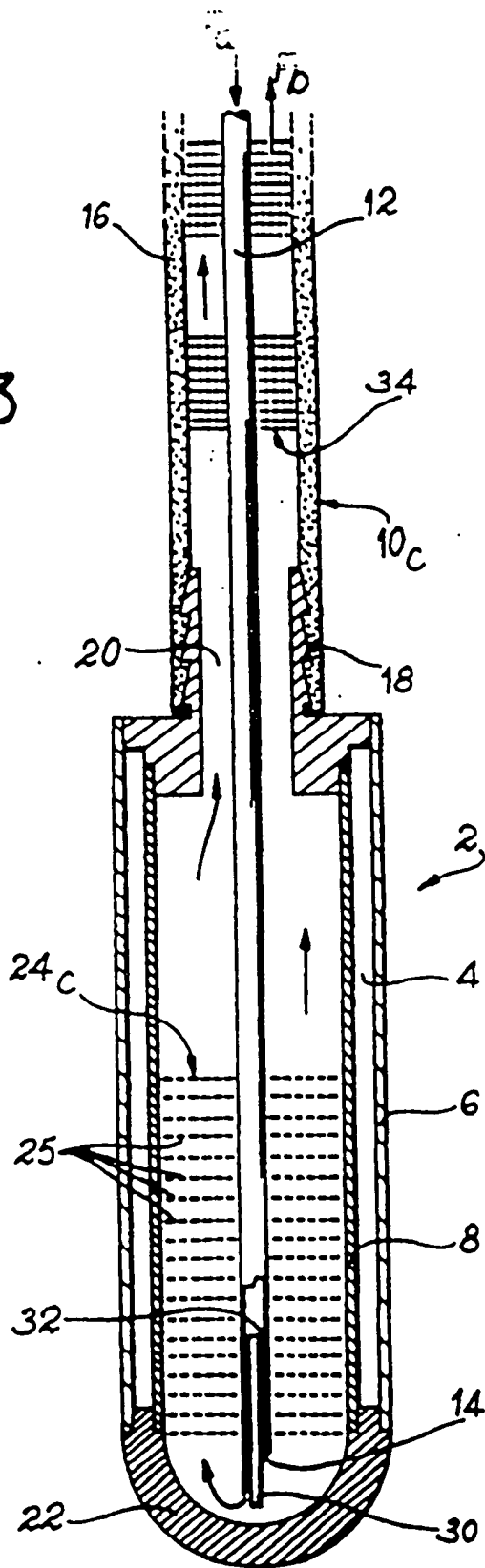


FIG. 4

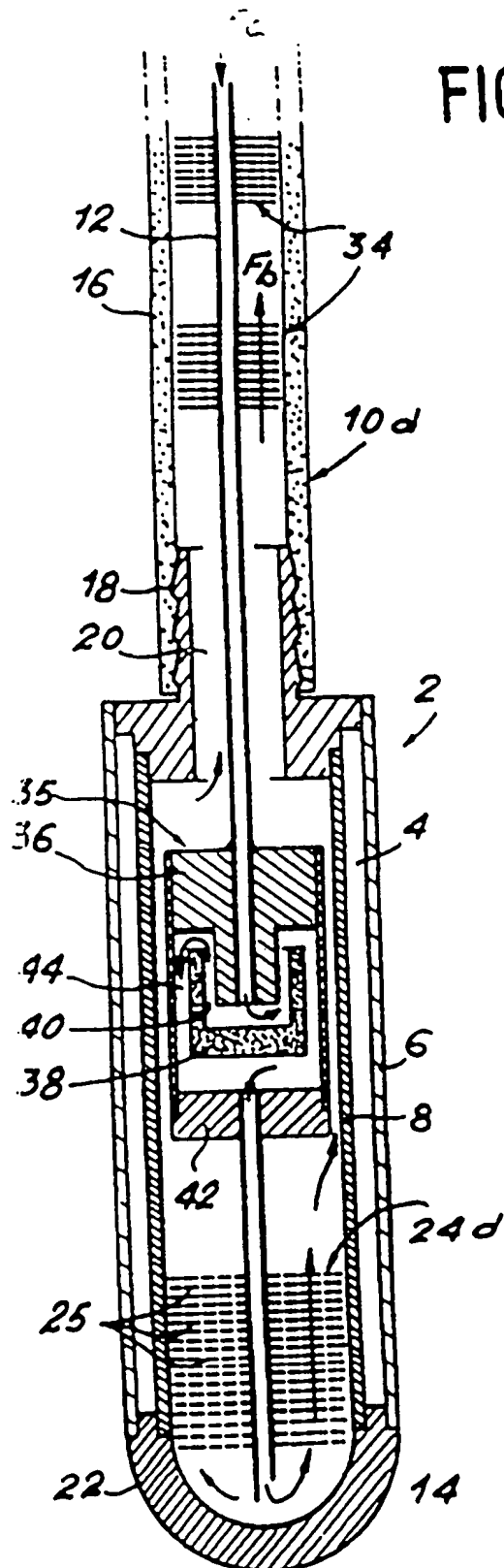


FIG. 5

